MAY 1 0 2002

K020692

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Donna A. Wolf
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: March 1, 2002

Name of Product: Emit® 2000 Vancomycin Assay

FDA Classification Name: Vancomycin Test System

Predicate Device: Emit® Vancomycin Assay (K881040)

Device Description:
The Emit® 2000 Vancomycin Assay is a homogeneous enzyme immunoassay intended for use in the quantitative analysis of vancomycin in human serum or plasma. Measurements obtained are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.

Serum or plasma is mixed with Reagent 1, which contains vancomycin labeled with the enzyme glucose-6-phosphate dehydrogenase (G6)DH). Subsequently, Reagent 2, which contains antibodies to vancomycin and the coenzyme nicotinamide adenine dinucleotide (NAD), is added. Vancomycin in the sample and vancomycin-labeled G6PDH compete for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the vancomycin concentration in the sample can be measured in terms of enzyme activity. Active enzyme converts oxidized NAD to NADH, resulting in an absorbance change that is measured spectrophotometrically. Endogenous G6PDH does not interfere because the coenzyme functions only with the bacterial (*Leuconostoc mesenteroides*) enzyme employed in the assay.

Intended Use: The Emit® 2000 Vancomycin Assay is a homogeneous enzyme immunoassay intended for use in the quantitative analysis of vancomycin in human serum or plasma. Measurements obtained are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.

Comparison to Predicate Device:
Conclusion: Split sample comparison between the Emit® 2000 Vancomycin Assay (modified) and the Emit® Vancomycin assay (K881040) gave a correlation coefficient of 0.99, slope of 0.96, and an intercept of -0.12 µg/dL when tested with 100 patient samples ranging from 5 to 50 µg/dL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 0 2002

Ms. Donna A. Wolf
Sr. Regulatory Affairs Specialist
Dade Behring Inc.
514 GBC Drive
Newark, DE 19702

Re: k020692
Trade/Device Name: Emit® 2000 Vancomycin Assay
Regulation Number: 21 CFR 862.3950
Regulation Name: Vancomycin test system
Regulatory Class: Class II
Product Code: LEH
Dated: March 1, 2002
Received: March 4, 2002

Dear Ms. Wolf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

Device Name: Emit® 2000 Vancomycin Assay

Indications for Use:

The Emit® 2000 Vancomycin Assay is a homogeneous enzyme immunoassay intended for use in the quantitative analysis of vancomycin in human serum or plasma. Measurements obtained are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020692

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)